REMARKS/ARGUMENTS

I. STATUS OF THE CLAIMS

Claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 are currently pending. No new matter is added with this amendment.

II. REJECTIONS UNDER 35 USC §103

The Examiner has maintained the rejection of claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 under 35 USC §103(a) as being unpatentable over Dubensky *et al.* (U.S. Patent No. 5,789,245) in view of Yu *et al.*, (Vaccine 15(12/13):1396-1404 (1997)) for the reasons of record.

The Examiner acknowledges that the invention as claimed is directed to a method for producing Ross River Virus (RRV) antigen/immunogenic compositions comprising, *inter alia*, the steps of infecting a cell culture with RRV, incubating the infected culture, and harvesting the RRV by filtering through two filters to purify the virus antigen. The first filter having a pore size between about 0.3 μm and about 1.5 μm. The second filter having a pore size between about 0.1 μm and about 0.5 μm. In addition, claims 27-31 are drawn to limitations of the method wherein the first filter is based on a positively charged matrix and the second filter is based on a hydrophilic matrix.

The Examiner cites Dubensky as disclosing a method for purifying an alpha-virus particle preparation by filtering the preparation through a first and second filter, wherein the first filter has a pore size of 0.8 μm and the second filter has a pore size of 0.65 μm. The Examiner continues to allege that the motivation to adjust the size of the filters is mere optimization. Specifically, the Examiner alleges that one of skill in the art would have known the size of RRV and adjusted the size of the filter accordingly to separate the unwanted components from the RRV.

With regard to the declaration of Otfried Kistner and Manfred Reiter filed April 13, 2006, the Examiner acknowledges that "[T]he Office recognizes that Applicant surprisingly discovered that the combination of filters (1.2 micron followed by 0.22 micron) resulted in a

pure RRV intermediate composition." (See, Office Action page 4). Although the claims encompass this embodiment, the Examiner contends that the claims also encompass other embodiments such as those described by Dubensky. Specifically, the Examiner alleges that one of skill in the art optimizing Dubensky's method, would be lead to practice the Applicant's invention.

The Applicants disagree. First, the filters used by Dubensky fall outside of the pore sizes claimed by the present invention. Specifically, the present invention requires that the second filter have a pore size between about 0.1 μm and about 0.5 μm. Dubensky uses a second filter having a pore size of 0.65 μm, which in contrast to the Examiner's assertions, falls well outside of the range presently claimed.

Second, the surprising effect for the full range of the pore sizes for the second filter has been shown over that of Dubensky. The declarants have stated in the declaration and shown in the table in the declaration that the Dubensky method "*cannot produce virus of the purity achieved by our method.*" (Emphasis added). As stated above, the Examiner acknowledges that the filter combination of 1.2 micron pore size followed by 0.22 micron pore size produces an RRV preparation that is surprisingly pure compared to that of Dubensky. The Applicants direct the Examiner's attention to the further surprising finding that even after filtering Dubensky's preparation with a 0.2 micron filter did not produce a result as pure as the claimed method using a 1.2 micron pore size followed by a 0.45 micron pore size. (*See,* table in declaration filed April 13, 2006). Surprisingly, using the claimed 2-step filtration method (with filter pore sizes near the top end of the claimed range) resulted in a preparation having 3-fold greater purity than the Dubensky's method followed by a third filtration step using a 0.2 μm filter. Specifically, the claimed method produced a preparation having 0.23 ng DNA/μg Protein, while the triple filtration of Dubensky (Dubensky's method followed by a 0.2 μm filtration) produced a preparation having 0.73 ng DNA/mg Protein. This is highly surprising and clearly demonstrates that the entire range of claimed pore sizes in the present invention yields an RRV preparation that is surprisingly pure compared to the method of Dubensky, even when optimized as shown by the addition of the 0.2 micron filter.

These findings make clear that the claimed method is more than mere optimization of the method of Dubensky, as alleged by the Examiner. Although Dubensky uses a first filter that falls within the range claimed by the present method (0.3 to 1.5), Dubensky did not appreciate the importance of the second filter as presently claimed (0.1 to 0.5 micron pore size). As detailed in the declaration and discussed *supra*, a first filter of 1.2 microns and a second filter of 0.45 microns (near the top end of the claimed range for the second filter) produced a purer preparation than that achieved using Dubensky's method followed by a 0.2 micron filter which is near the lower end of the claimed range for the second filter. This clearly demonstrates why the present invention is not obvious in light of the cited references.

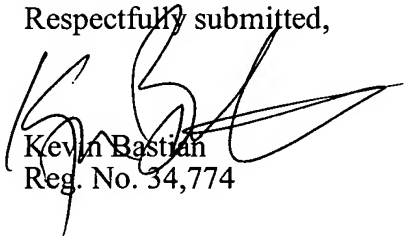
In light of the above, the Applicants respectfully request that the Examiner withdraw the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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